UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,526	02/09/2001	Imre Kovesdi	206060	8376

23460 7590 05/19/2005

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6780

EXAMINER	
TRAN, MY CHAU T	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/780,526	KOVESDI ET AL.	
	Examiner	Art Unit	
	MY-CHAU T. TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12 and 54* is/are pending in the application.

4a) Of the above claim(s) *7,8,10 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,12 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.D-D

DETAILED ACTION

Application and Claims Status

1. Applicant's amendment and response filed 02/28/2005 is acknowledged and entered. Claim 2 has been canceled. Claim 1 has been amended. Claim 54 has been added.

2. Claims 13-53 were canceled by the amendment filed on 05/14/2004.

3. Claims 1, 3-12, and 54 are pending.

Election/Restrictions

4. Applicant has elected the following species for the elected invention (Claims 1, 3-12, and 54) in the reply filed on 04/09/2003:

a. A single specific species of first gene product: vascular endothelial growth factor (VEGF).

b. A species of second gene product: proteins.

5. Claims 7-8, and 10-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to ***nonelected species***, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/09/2003.

6. Claims 1, 3-6, 9, 12, and 54 are treated on the merit in this Office Action.

Priority

7. It is noted that this instant application claims benefit to three provisional applications under 35 U.S.C 119(e). They are 60/181,321 filed 2/9/2000; 60/205,269 filed 5/18/2000; and 60/209,158 filed 6/2/2000. Thus, the instant application is granted the benefit of priority for all three provisional applications under 35 U.S.C 119(e).

8. Claims 1, 3-6, 9, 12, and 54 are treated on the merit in this Office Action.

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1, 3-6, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by van Zonneveld et al. (US Patent 6,447,768 B1; *filing date 12/29/1999*). *NOTE: this rejection is modified to address the amendment of claim 1 and the cancellation of claim 2, wherein the limitation of claim 2, i.e. the viral vectors are adenoviral vectors, is added to claim 1.*

The instant invention recites a library of adenoviral vectors. The library of adenoviral vectors wherein each member comprises a common first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product that varies between the members of the library.

van Zonneveld et al. disclose nucleic acid delivery carrier that includes virus vectors such as adenoviral vectors and adeno-associated viral vectors (see e.g. Abstract; col. 3, lines 18-30, and 51-56). The viral vectors comprise recombinant adenoviral vectors containing a common

nitric oxide synthase (refers to the first gene product of the instant claim 1), a CMV promoter (refers to instant claim 3), and a sequence encoding either bFGF or VEGF (refers to the second gene product and the limitation wherein the second gene product varies between the members of the library of the instant claim 1) (see e.g. col. 5, lines 5-24; col. 6, line 23-28). Thus the viral vectors of van Zonneveld et al. anticipate the presently claimed library of viral vectors.

New Rejection(s) – Necessitated by Amendment

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-6, 12, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Zonneveld et al. (US Patent 6,447,768 B1; *filing date 12/29/1999*).

The instant invention recites a library of adenoviral vectors. The library of adenoviral vectors adenoviral wherein each member comprises a common first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product that varies between the members of the library.

Claim 54 recite a specific type of adenovirus that is serotype 35.

van Zonneveld et al. disclose nucleic acid delivery carrier that includes virus vectors such as adenoviral vectors and adeno-associated viral vectors (see e.g. Abstract; col. 3, lines 18-30, and 51-56). The viral vectors comprise recombinant adenoviral vectors containing a common nitric oxide synthase (refers to the first gene product of the instant claim 1), a CMV promoter (refers to instant claim 3), and a sequence encoding either bFGF or VEGF (refers to the second gene product and the limitation wherein the second gene product varies between the members of the library of the instant claim 1) (see e.g. col. 5, lines 5-24; col. 6, line 23-28). The adenovirus includes subgroup B adenovirus (see e.g. col. 3, lines 60-63).

The adenovirus vectors of van Zonneveld et al. differ from the presently claimed invention by failing to include the type of adenovirus that is serotype 35.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the type of adenovirus that is serotype 35 in the adenovirus vectors of van Zonneveld et al. One of ordinary skill in the art would have been motivated to include the type of adenovirus that is serotype 35 in the adenovirus vectors of van Zonneveld et al. because van Zonneveld et al. specifically disclose the use of subgroup B adenovirus (see e.g. col. 3, lines 60-63) and serotype 35 is a known type of subgroup B adenovirus. Moreover, the instant specification discloses that serotype 35 adenovirus is well known and commercially available type of subgroup B adenovirus, i.e. "*Adenoviral stocks that can be employed as a source of adenoviral genomes can be amplified from the adenoviral serotypes 1 through 51,*

which are currently available from the American Type Culture Collection (ATCC, Manassas, VA), or from any other serotype of adenovirus available from any other source. For instance, an adenovirus can be of subgroup A (e.g., serotypes 12, 18, and 31), subgroup B (e.g., serotypes 3, 7, 11, 14, 16, 21, 34, and 35), subgroup C (e.g., serotypes 1, 2, 5, and 6), subgroup D (e.g., serotypes 8, 9, 10, 13, 15, 17, 19, 20, 22-30, 32, 33, 36-39, and 42-47), subgroup E (serotype 4), subgroup F (serotypes 40 and 41), or any other adenoviral serotype" (see paragraph [0017], lines 8-16), and that any type of adenovirus can be use for the adenovirus vectors. Thus, it would be obvious to one skilled in the art to use different type of adenovirus for the adenovirus vectors since it would be a choice of experimental design and is considered within the purview of the cited prior art.

Withdrawn Rejection(s)

14. The rejection of claims 1, and 3 under 35 USC 102(b) as being anticipated by Schatz et al. (US Patent 5,733,731) has been withdrawn in light of applicant's amendments of claim 1 and cancellation of claim 2

15. The rejection of claims 1, and 3 under 35 USC 102(e) as being anticipated by Schatz et al. (US Patent 6,156,511; *filing date 1/21/1998*) has been withdrawn in light of applicant's amendments of claim 1 and cancellation of claim 2, wherein the limitation of claim 2, i.e. the viral vectors are adenoviral vectors, is added to claim 1.

Response to Arguments

16. Applicant's argument directed to the rejection under 35 USC 102(e) as being anticipated by van Zonneveld et al. (US Patent 6,447,768 B1; *filing date 12/29/1999*) for claims 1, 3-6, and 12 was considered but they are not persuasive for the following reasons.

Applicant contends that the adenoviral vectors of van Zonneveld et al. do not anticipate the presently claimed invention because "*the van Zonneveld patent does not disclose, or even suggest, a library of such adenoviral vectors wherein the first heterologous DNA is common to each member of the library of adenoviral vectors and the second heterologous DNA varies between the members of the library of adenoviral vectors, as required by the pending claims.*" Thus, the adenoviral vectors of van Zonneveld et al. do not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the adenoviral vectors of van Zonneveld et al. do anticipate the presently claimed invention. First, van Zonneveld et al. does disclose adenoviral vectors "*wherein the first heterologous DNA is common to each member of the library of adenoviral vectors and the second heterologous DNA varies between the members of the library of adenoviral vectors*" (see col. 6, lines 28-33). Second, the term "library" as define by the Webster's Dictionary is a 'collection' of individual entities and the term "collection" as define by the Webster's Dictionary is a group of objects to be viewed or studies. The adenoviral vectors of an Zonneveld et al. is an implicit disclosure of the term 'library' for this disclosure would encompasses the definition of the term "library" and the term "collection" as define by the Webster's Dictionary. Therefore, the adenoviral vectors of van Zonneveld et al. do anticipate the presently claimed library of adenoviral vectors, and the rejection is maintained.

17. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

18. The following is a statement of reasons for the indication of allowable subject matter:

The limitation that the first gene product is a vascular endothelial growth factor (VEGF) of the claimed library of adenoviral vectors wherein each members of the library comprises a common first heterologous DNA encoding a first gene product and a second heterologous DNA encoding a second gene product that varies between the members of the library is not taught or suggested by the cited prior art.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PADMASHRI PONNALURI
PRIMARY EXAMINER

mct
May 14, 2005